Translation of European patent application No 0 601 328 A1
Applicants: Siemens Elema AB
Title: Defibrillation system

Abstract

The invention concerns a defibrillation system comprising a defibrillator to which at least two defibrillation electrodes are connected, wherein there is provided at least one defibrillation electrode for intracardial placement. That defibrillation electrode includes a flexible electrode cable having at least one elongated, electrically insulated conductor and an electrode head disposed at the distal end of the electrode cable, with at least one defibrillation surface for the transmission of defibrillation pulses to the heart. The defibrillation system further includes monitoring means which decide if the defibrillator is to output one or more defibrillation pulses. In order to obtain a defibrillation system with an intracardial defibrillation electrode of that kind, whose defibrillation surface is comparatively large and can be distributed in the heart in such a way that damage to the heart is avoided at the same time as optimum defibrillation can be achieved, and in which the defibrillation electrode does not influence the flow of blood in the heart in the period in which it is not outputting any stimulation pulses, it is proposed in accordance with the invention that the electrode head (14, 17) is of such a structure that it is expandable and that the defibrillator (1) has control means (7) which if necessary by way of the electrode cable (4, 5) influence the electrode head (14, 17) in such a way that it expands.

The invention concerns a defibrillation system comprising a defibrillator to which at least two defibrillation electrodes are connected, wherein there is provided at least one defibrillation electrode for intracardial placement, and that defibrillation electrode includes a flexible electrode cable having at least one elongated, electrically insulated

conductor and an electrode head disposed at the distal end of the electrode cable, with at least one defibrillation surface for the transmission of defibrillation pulses to the heart, and wherein the defibrillation system includes monitoring means which decide if the defibrillator is to output one or more defibrillation pulses.

A defibrillation system of that kind is known from US patent specification No 4 662 377. Connected to the defibrillator are two defibrillation electrodes in which the one electrode is applied subcutaneously and the other electrode is applied intracardially. The electrode head of the intracardially applied defibrillation electrode has a coiled conductor whose diameter approximately corresponds to the outside diameter of the electrode cable, the conductor extending along a relatively long part of the distal end of the electrode. The disadvantage of such a defibrillation electrode is that its defibrillation surface is comparatively small in comparison with the magnitude of that current which is fed to that surface upon the output of a defibrillation pulse. As the defibrillation surface generally bears against the wall of the heart, the heart can suffer from burn injuries. The size, application and concentration of the defibrillation surface at one location in the heart do not afford an optimum defibrillation effect.

US patent specification No 5 010 894 describes a defibrillation electrode which is intended for intracardial placement. The electrode head includes a number of outwardly directed preshaped flexible conductors which serve as defibrillation surfaces, wherein the proximal ends of the conductors are secured in mutually juxtaposed relationship to a common connecting element simultaneously with their distal ends being fixedly mounted in mutually juxtaposed relationship to a further common connecting element. Before the electric cable is inserted into the heart by way of a vein, the electrode head is extended by means of a bar in such a way that the conductors come to lie in closely mutually juxtaposed relationship, with the outside diameter of the electrode head being only

somewhat larger than the outside diameter of the electrode cable. After the electrode bar has been inserted into the heart, the bar can be withdrawn. When that happens, the conductors expand laterally so that they come to lie against the surrounding wall resiliently thereagainst over a considerable section of their length. The current which is fed to the conductors can now be uniformly distributed by that defibrillation electrode, in which case the conductors together form a comparatively large defibrillation surface. That can prevent the occurrence of burns on the surrounding wall of the heart. An optimum defibrillation effect can also be achieved by virtue of the fact that the conductors are also uniformly distributed in the heart. As the electrode head is permanently disposed in the heart at least the conductors must have extremely good material properties so that they can follow the movements of the heart over a prolonged period of time without them or the heart suffering damage. In addition a comparatively large electrode head of that kind can impede the flow of blood in the heart.

The object of the invention is to provide a defibrillation system having an intracardial defibrillation electrode of the kind set forth in the opening part of this specification, whose defibrillation surface is comparatively large and can be distributed in the heart in such a way that damage to the heart is avoided simultaneously with the attainment of an optimum defibrillation effect. The invention also seeks to provide that the defibrillation electrode does not influence the flow of blood in the heart in the period in which it does not output any stimulation pulses.

According to the invention that object is attained in that the electrode head is of such a structure that it is expandable and that the defibrillator has control means which if necessary influence the electrode head by way of the electrode cable in such a way that it expands. When the monitoring means which sense the state of the heart indicate the need for heart defibrillation, the electrode head is expanded by means of the above-mentioned control means so that the defibrillation surface or the

surfaces come to bear against the surrounding wall of the heart or in the proximity thereof, whereupon defibrillation pulses can be applied to the heart. When thereafter the heart returns to a normal state the electrode head is returned to its original position by means of the control means. In that original position, the electrode head is of a shape which does not influence the flow of blood in the heart. When the electrode head is moved into such a passive position, neither the electrode head nor the surrounding wall of the heart can come to harm. The shape of the electrode head in a passive position thereof is similar to a tubular body which forms a prolongation of the electrode cable in the longitudinal direction thereof and which is disposed approximately in the center of the ventricle.

In a development of the invention, it is proposed that the electrode head of the defibrillation electrode comprises an inflatable material which is preferably elastic. That provides that the electrode head in the inflated condition can bear against a large part of the surrounding wall of the heart.

In an advantageous embodiment of the invention, it is proposed that the defibrillation surfaces are formed on the inflatable material from wire-shaped conductors which are arranged in such a way that they permit expansion of the electrode head. The conductors are preferably distributed uniformly over the electrode head. It is possible to achieve a desired size of defibrillation surface by virtue of the choice of the number of conductors and a choice of the size thereof.

In accordance with a further embodiment of the electrode head of the defibrillation electrode, the electrode head comprises at least two elongated flexible limb-shaped parts which entirely or partially serve as defibrillation surfaces, of which the one ends are secured to the electrode cable and which at least partially bear against each other, the limb-shaped parts being expandable by means of a separating member. By virtue of this structure each limb-shaped part may be of a comparatively large

defibrillation surface area. In addition, in a defibrillation operation, depending on the length and the number of the limb-shaped parts, the electrode head can bear against the major part of the surrounding wall of the heart in the ventricle.

In accordance with the invention the separating member may preferably be an inflatable balloon-like part which is connected to the electrode cable and disposed between the limb-shaped parts.

A structurally simple configuration of the invention is one in which the control means are a pump which supplies a gas or a liquid by way of a duct in the electrode cable, the electrode head or the balloon-like part, or removes a gas or a liquid from the electrode head or the balloon-like part by way of the duct.

It is also proposed in accordance with the invention that the monitoring means influence the control means in such a way that expansion of the electrode head takes place before a defibrillation pulse is outputted. That procedure ensures optimum defibrillation of the heart.

The invention is described in greater detail hereinafter by means of a number of embodiments illustrated in the drawings in which:

Figure 1 shows a defibrillation system with an intracardial defibrillation electrode according to the invention,

Figure 2 shows a further embodiment of the defibrillation electrode shown in Figure 1,

Figures 3 and 4 show further embodiments of an intracardial defibrillation electrode according to the invention, and

Figure 5 shows a block circuit diagram of a defibrillation system according to the invention.

Referring to Figure 1, shown therein is a defibrillation system having a defibrillator 1 to which two defibrillation electrodes 2 and 3 are connected, wherein the one defibrillation electrode 2 is placed intracardially and the other defibrillation electrode 3 is placed for example subcutaneously. The other defibrillation electrode 3 or a third defibrillation

electrode in such a defibrillation system can also be disposed in the region of the vena cava superior, such a defibrillation electrode being of a shape which is suited to that region. The defibrillation electrodes 2, 3 are connected by way of electrode cables 4, 5 to a pulse generator 6 disposed in the defibrillator 1. The intracardially applied defibrillation electrode 2 is also connected to control means 7. The defibrillation system also includes monitoring means 8 to which an intracardially placed sensor electrode 9 is connected. The above-mentioned pulse generator 6 and the control and monitoring means 7 and 8 are described in greater detail hereinafter with reference to this Figure and also Figure 5.

The intracardial defibrillation electrode 2 comprises the above-mentioned flexible electrode cable 4 which includes an elongated conductor 10 whose outside is provided with an insulating layer 11 and whose inside forms a duct 12. This embodiment is represented by means of the longitudinal section 13 on the electrode cable 4. Disposed at the distal end of the electrode cable 4 is an electrode head 14 comprising an inflatable material which is preferably elastic. The defibrillation surfaces on the inflatable material are formed from wire-shaped conductors 15 which are arranged in such a way that they permit the electrode head 14 to expand. In this embodiment the wire-shaped conductors 15 which are connected to the conductor 10 extend from the fixing location on the electrode cable 4 to the distal end of the electrode head 14 where they are connected together in order to avoid voltage differences between the wire-shaped conductors 15.

When the monitoring means 8 indicate fibrillation due to signals from the sensor electrode 9, that information is passed to the control means 7 which by way of the electrode cable 4 immediately expands the electrode head 14 so that the outside wall thereof, with the wire-shaped conductors 15, bears tightly against the surrounding wall of the heart, as shown in Figure 2. When the control means 7 have moved the electrode head 14 into that active position, that information is passed to the pulse

generator 6 which then outputs defibrillation pulses to the heart by way of the defibrillation electrodes 2 and 3. The control means 7 for the intracardially placed defibrillation electrode 2 are a pump, for example a piston pump, which feeds a gas or a liquid, for example saline solution, to the electrode head 14 by way of the duct 12 of the electrode cable 4. The pump 7 which is diagrammatically shown in Figure 1 is intended to illustrate that, when the defibrillation electrode 2 is contracted in a position as shown in Figure 1, the piston 16 is in a position which is shown by the solid contour lines thereof. The space in the pump 7 and also the duct 12 of the electrode cable 4 are here filled with a gas or a liquid. Before defibrillation of the heart is to be effected, the piston 16 is displaced into a position as shown by the dash-dotted contour lines, in which case the gas or the liquid is transported to the electrode head 14 which expands, as described with reference to Figure 2. When the sensor electrode 9 again displays normal cardiac activity, that result is passed by way of the monitoring means 8 in part to the pulse generator 6 which then stops the output of defibrillation pulses and in part to the pump 7, in which case the pump 7, by means of the piston 16, sucks the gas or the liquid out of the electrode head 14 so that the electrode head 14 is contracted into its original passive position.

Figure 3 shows an intracardial defibrillation electrode having an electrode head 17 which differs in terms of its structure from the electrode head shown in Figures 1 and 2. This electrode head 17 includes a number of limb-shaped parts 18, 19 which are connected to the conductor 10 (not shown here) of the electrode cable 4 and which serve as defibrillation surfaces. Figures 3 and 4 only show two limb-shaped parts 18 and 19 for the sake of clarity of the drawing. The electrode head 17 can however preferably be provided with a larger number of such parts 18, 19 which are secured in a uniformly distributed array to the distal end of the electrode cable. The limb-shaped parts 18, 19 are of such a material and of such a shape that, when they are moved into a passive position as

shown in Figure 3, they at least partially come to bear against each other. An inflatable balloon-like part 20 is also secured to the distal end of the electrode cable 4 between the limb-shaped parts 18, 19. The balloon-like part 20 is connected to the pump 7 by way of the duct in the electrode cable 4. Before defibrillation is to be implemented, the balloon-like part 20 is inflated in a manner described with reference to Figures 1 and 2 so that the limb-shaped parts 18, 19 expand and bear against the surrounding wall of the heart, in which case defibrillation pulses can be outputted. The fact that the inflatable balloon-like part 20 can be made comparatively small means that the pump 7 can also be correspondingly small. After defibrillation of the heart the electrode head 17 moves back into its original passive position by the pump 7 sucking the gas or the liquid out of the part 20.

In a further embodiment (not shown) of the defibrillation electrode 2 the movements of the limb-shaped parts 18, 19 can also be effected by means of a thin wire which is connected by way of the duct 12 of the electrode cable 4 to a motor-driven roller disposed in the defibrillator 1 and onto and from which the wire can be wound and unwound. In that case the wire and the motor-driven roller are to replace the pump 7.

Figure 5 shows a block circuit diagram of the described defibrillation system. In this embodiment as shown in Figure 5 the cardiac signals are sensed by the sensor electrode 9. They are applied to the monitoring means 8 which in known manner sense whether the heart is suffering from defibrillation. If that is the case and a defibrillation shock is to be outputted, a signal is passed by way of a line 21 to an expansion logic system 22 which is a part of the control means 7. The output signal from the expansion logic system 22, by way of a line 23 and possibly by way of an amplifier 24, controls a pump 25 in order to expand the electrode 2 by way of the electrode cable 4 in the above-described manner. The status of the pump 25 is signaled back to the expansion logic system 22 by way of a line 26. The expansion logic system 22 establishes that the electrode

2 is expanded and by way of an output line 27 outputs a control pulse to the shock logic system 28 which is a part of the pulse generator. Parameters such as for example the energy level can be programmed in the shock logic system 28 by means of a line 29, as already indicated. The shock logic system 28 generates an output signal which, by way of a line 30, controls an end stage for the generation of a defibrillation pulse which is fed by way of the conductor 10 to the electrode 2 which is expanded at that time. The shock logic system 28 also generates a signal which indicates when the shock is concluded. That signal is passed by way of a line 32 to the expansion logic system 22 which, in dependence on the signals from the monitoring means 8, decides whether the cardiac fibrillation was interrupted by the defibrillation pulses and those pulses compelled the heart to resume its normal activity or whether fibrillation still obtains and a further shock pulse should be outputted. In dependence thereon, the electrode is held in its expanded position, alternatively a signal is produced which by way of the pump 25 puts the electrode into the shape which it is intended to have as long as no shock pulse is to be outputted to the heart.

List of references

1	defibrillator
2, 3	defibrillation electrode
4, 5	electrode cable
6	pulse generator
7, 25	control means, pump
8	monitoring means
9	sensor electrode
10	conductor
11	insulating layer
12	duct
13	longitudinal section
14, 17	electrode head
15	wire-shaped conductor, defibrillation surface
16	piston
18,19	limb-shaped parts
20	balloon-like part, separating member
21, 23, 26	line
29, 30, 32	line
22	expansion logic system
24	amplifier
27	output line
28	shock logic system
31	end stage

Claims

1. A defibrillation system comprising a defibrillator to which at least two defibrillation electrodes are connected, wherein there is provided at least one defibrillation electrode for intracardial placement, and that defibrillation electrode includes a flexible electrode cable having at least one elongated, electrically insulated conductor and an electrode head disposed at the distal end of the electrode cable, with at least one defibrillation surface for the transmission of defibrillation pulses to the heart, and wherein the defibrillation system includes monitoring means which decide if the defibrillator is to output one or more defibrillation pulses, characterized in that the electrode head (14, 17) is of such a structure that it is expandable and that the defibrillator (1) has control means (7) which if necessary influence the electrode head (14, 17) by way of the electrode cable (4, 5) in such a way that it expands.

2. A defibrillation system as set forth in claim 1 characterized in that the electrode head (14) of the defibrillation electrode (2) comprises an inflatable material which is preferably elastic.

3. A defibrillation system as set forth in claim 2 characterized in that the defibrillation surfaces (15) are formed on the inflatable material from wire-shaped conductors which are arranged in such a way that they permit expansion of the electrode head (14).

4. A defibrillation system as set forth in claim 1 characterized in that the electrode head (17) of the defibrillation electrode (2) includes at least two elongated flexible limb-shaped parts (18, 19) which entirely or partially serve as defibrillation surfaces whose one ends are secured to the electrode cable (4) and which at least partially bear against each other, the limb-shaped parts (18, 19) being expandable by means of a separating member (2).

5. A defibrillation system as set forth in claim 4 characterized in that the separating member (20) is an inflatable balloon-like part which is connected to the electrode cable (4) and disposed between the limb-shaped parts (18, 19).

6. A defibrillation system as set forth in one of claims 2 through 5 characterized in that the control means (7) are a pump which by way of a duct (12) in the electrode cable (4) feeds a gas or a liquid to the electrode head (14) or the balloon-like part (17) or by way of the duct removes a gas or a liquid from the electrode head (14) or from the balloon-like part (17) respectively.

7. A defibrillation system as set forth in one of claims 1 through 6 characterized in that the monitoring means (8) influence the control means (7) in such a way that expansion of the electrode head (14, 17) occurs before a defibrillation pulse is outputted.